Comparison of Oxidation Rates and Effects in Sequentially Annealed Tibial, Patellar, and Acetabular Bearings

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Disclosures:
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Introduction: Retrieval analysis of crosslinked UHMWPE bearings reveals a difference in the rate of in vivo oxidation between tibial and acetabular devices, with tibial bearings oxidizing at a significantly faster rate than acetabular components. However, in most cases, the materials used in acetabular and tibial devices are different. As a result, for some materials it is difficult to parse out the effects of joint environment from the effects of material processing.

There are currently only a few devices on the market that are used in both the hip and the knee, including a 9.5 MRad electron beam irradiated and remelted material (Durasul, Zimmer Inc., Warsaw, IN) and a 9 MRad sequentially irradiated and annealed material (X3, Stryker Inc., Mahwah, NJ). Comparing the performance of these materials in the different joint environments allows for a more controlled study of the effects of the joint on oxidation. X3 is interesting among these materials because it is implanted in large numbers in tibial inserts and acetabular liners, as well as in patellar prostheses.

Previous work has demonstrated a difference in the oxidation rate between tibial and acetabular X3 devices. However, from that work it remains unclear whether the different joint environments encourage oxidation by different mechanisms, or whether the increased stress or other environmental factors accelerate the reaction in the knee. If contact stress is the primary indicator for oxidation rate, then one would expect patellar components, which experience stresses greater than acetabular devices but less than tibial inserts, to oxidize at a rate between the tibial and acetabular oxidation rates.

Additionally, oxidation in tibial components decreases the measured crosslink density at a linear rate. If the mechanism of oxidation is the same, one would expect that crosslink density should decrease with increasing oxidation in acetabular and patellar components along the same trend.

The aims of this study are to determine the relative rate of oxidation in sequentially annealed patellar components compared to tibial or acetabular devices and to determine the relationship between oxidation and crosslink density for each device type. The hypothesis is that patellar components will oxidize at a rate between acetabular and tibial devices, and that crosslink density will change with oxidation at the same rate for all three device types.

Methods: 66 retrieved UHMWPE bearings were evaluated in this study, including 25 acetabular liners, 35 tibial inserts, and 6 patellar components. The same sequentially-annealed polyethylene material was utilized in all devices (X3, Stryker Inc., Mahwah, NJ). In vivo duration ranged from 0.3 to 77 months, with an average of 25.5 months. No devices were removed for failure of the polyethylene.

The ketone peak height, as measured by FTIR, was used as an indicator of oxidation. Line scans were performed on a cross-section from the articular surface to the backside of the device. The maximum ketone value was determined for analysis of oxidation versus time, and the average ketone across the first 2 mm from the articular surface was calculated for comparison to crosslink density measurements. Crosslink density was measured by a gravimetric gel swell technique utilizing 2 mm cubes cut from the articular surface.

In determining relationships between variables, an exponential fit was utilized for analysis of oxidation versus in vivo duration, since this relationship has previously been shown to be exponential for other materials. Linear regression was used for all other relationships, and regression coefficients were tested against each other to determine statistical differences between trends.

Results: The exponential regression was significant for both the acetabular and tibial data (Acetabular: R=0.60, p<0.01; Tibial: R=0.84, p<0.01), while the fit for the patellar data was not significant (R=0.58, p=0.23) (Figure 1). The coefficients for the acetabular and tibial fits were significantly different (p<0.01), with tibial components oxidizing at a faster rate. Tibial components exhibited a significant trend of decreasing crosslink density versus duration (R=0.65, p<0.01) while the regression was not significant for acetabular of patellar components (Acetabular: R=0.20, p=0.33; Patellar: R=0.26, p=0.61) (Figure 2).

Both tibial and acetabular components had significant linear relationships between crosslink density and average ketone oxidation (Acetabular: R=0.50, p=0.01; Tibial: R=0.66, p<0.01) while the patellar relationship was not significant (R=0.17, p=0.74) (Figure 3). The coefficients for the acetabular and tibial relationships were significantly different (p<0.01).

Discussion: This study was constrained by the small sample set of patellar components compared to tibial or acetabular devices, which limited statistical power. However, even with the small number of devices, early observations can still be made about the
The difference in oxidation rates observed in this study between tibial and acetabular devices has been previously established for sequentially annealed and other highly cross-linked UHMWPE materials. It has been hypothesized that the higher stress state on the tibial condyle leads to a more rapid oxidation. Depending upon implant design, stresses on the patella could be expected to fall between the high stress in the tibial condyle and the relatively low stress in the acetabular cup. If oxidation rates are dependent upon stress, one would expect oxidation in the patella to occur at a rate between those of the acetabular and tibial devices. While there are not enough devices to determine a statistical trend, visual inspection of Figure 1 indicates that early oxidation in sequentially annealed patellae is indistinguishable from that in acetabular or tibial devices. Examination of longer duration patellar components will be necessary to determine the relative oxidative rates.

The relationship between crosslink density and in vivo oxidation in sequentially annealed tibial inserts was previously established, but given the significant difference in oxidation rates for sequentially annealed tibial, patellar and acetabular components, it was unclear whether the oxidative mechanisms in these component types were the same.

As observed in Figure 3, crosslink density decreased with increasing oxidation for all three device types, but there was a statistically significant different between the trends for tibial and acetabular components. However, on a closer look, the acetabular data set has a single data point with average ketone oxidation nearly twice as large as the next highest data point. Such an outlier has significant leverage on the regression and may skew the trend line. If this point is excluded, the trends for tibial and acetabular crosslink density versus oxidation are not statistically different (p = 0.22). Once again, there were not enough patellar devices to establish a statistical trend, but visual inspection of Figure 3 suggests that these devices are also following the same trend.

The results of this study suggest that while differing stress or other factors in the tibia, patella and acetabulum may influence the rate of in vivo oxidation in sequentially annealed bearings, the underlying mechanism remains the same across all three bearing types.

**Significance:** While the phenomenon of in vivo oxidation in sequentially annealed UHMWPE bearings is now well established, differing oxidation rates in acetabular and tibial bearings suggest that our understanding of the oxidative mechanism remains incomplete. The results of this study suggest that while differing environments in the different joint types may either accelerate or retard the reaction rate, the underlying mechanism of oxidation is the same for all sequentially annealed bearings.

**Acknowledgments:**

**References:**
Figure 1: Maximum ketone oxidation (1715 cm$^{-1}$/1368 cm$^{-1}$) versus in vivo duration for sequentially annealed (X3) UHMWPE bearings in the tibia, acetabulum, and patella. The rates of oxidation in tibial and acetabular components are statistically different ($p < 0.005$).
Figure 2: Crosslink density versus in vivo duration for sequentially annealed (X3) bearings retrieved from the tibia, patella and acetabula. Tibial devices exhibited a significant linear relationship ($p < 0.005$) while neither patellar nor acetabular components exhibit a
Figure 3: Crosslink density versus average ketone oxidation for retrieved sequentially annealed (X3) tibial, acetabular, and patellar bearings. The coefficients for the linear trends for tibial and acetabular components are significantly different ($p = 0.01$).